Individual Case Safety Report

10079154-01-00-01

CDER

Voluntary by user-facilities, distributors and manufacturers MANDATORY reporting

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

Mfr Report #	
UF/Importer Report #	
546515	FDA Use Only

FORM FDA 3500A (2/13)

Page 1 of 1

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6) In confidence	52 Years or Date of Birth: (b) (6)	☐ Female ☑ Male	lbs or 90 kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- ☐ Death: (mm/dd/yyyy)
- ☐ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)
03/09/2014	03/31/14

5. Describe Event or Problem

52 yo man with hepatitis C/cirrhosis admitted on (b) (6) with pneumococcal bacteremia, successfully treated, but then developed severe C. difficile infection which was resistant to treatment with po vancomycin, IV metronidazole, and vancomycin enemas. Complicated by ileus, which eventually resolved but continued to have high volume diarrhea. Under fecal transplant via nasoduodenal tube (confirmed to be in the 3rd/4th portion of the duodenum) on 03/06/14. Diarrhea improved. On (b) (6) required transfer to ICU for septic shock. Blood cultures grew 2 strains of pan-susceptible E. coli. Peritoneal fluid also grew E. coli. Treated with vasopressors and antibiotics and transferred back to floor on (b) (6) Remains hospitalized for an unrelated problem (possible thigh abscess).

CTU

APR 14 2014

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

Blood cultures on (b) (6)
Peritoneal fluid culture on (b) (6)

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Hepatitis C + alcohol induced cirrhosis
Schizophrenia

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)

#1 Human stool obtained from OpenBiome (Fecal MicroBiota)

#2

2. Dose, Frequency & Route Used	3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1 25 mL via Dobhoff tube	#1 03/06/14
#2	#2

4. Diagnosis for Use (Indication)

#1 Severe C. difficile colitis

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

Prior to fecal transplant was treated with po vancomycin, IV metronidazole, and vancomycin enemas

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date (mm/dd/yyyy)	7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)

☐ Yes ☐ No ☐ Returned to Manufacturer on: (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Physician	☐ Yes ☐ No ☐ Unk.

Individual Case Safety Report

10079170-01-00-01

CDER

essional Report

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

' reporting of
ct problems and
product use errors 1/3

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence # 546617

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	64 Years (b) (6)	☑ Female ☐ Male	234 lb or ____ kg

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☑ Death: (b) (6) *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - Initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
02/26/2014	04/10/2014

5. Describe Event, Problem or Product Use Error

on: The patient was initially salvaged in the ICU from unresponsive fulminant C.diff with FMT given by EGD. She then went to an ECF where her C.diff recurred and she was started on Vancomycin 125 QID, the appropriate dose. She wasn't responding to outpatient oral Vancomycin so a colonoscopy was performed to insure C. diff as the cause and to rule out other causes of her diarrhea. Colonoscopy revealed pseudomembranous colitis suggesting recurrent severe C.diff and FMT was performed. When I was asked about this patient I suggested an increase of Vancomycin to 500mg QID and to go ahead with FMT as ...

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

1. Fecal transplant 02/21/2014.
2. History of hypertension.
3. History of hyperlipidemia.
4. Chronic low back pain.
5. Chronic obstructive pulmonary disease.
6. History of pseudomembranous colitis.
7. History of septic shock from UTI and C. difficile.
8. History of B12 deficiency.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Name: Fecal Microbiota (MicroBiota)
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*

#1 02/21/2014 - 02/21/2014
#2

4. Diagnosis or Reason for Use *(Indication)*

#1 C.Diff Infection
#2

5. Event Abated After Use Stopped or Dose Reduced?	8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name CTU
3. Manufacturer Name, City and State APR 14 2014

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)* 7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER *(See confidentiality section on back)*

(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Nurse	☐ Manufacturer ☑ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

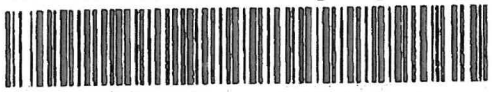
Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

546547

B.5. **Describe Event or Problem** *(continued)*

... it might assist treatment as it did initially in the ICU. They should have continued her Vancomycin 500mg QID and used the FMT as an adjunctive treatment, not a primary treatment. The treating GI physician however did not continue her Vancomycin after the FMT, thinking that the FMT was enough and it is not. He used the FMT as the primary treatment and that was not the appropriate treatment. After a few days the patient was readmitted with fulminant C.diff colitis. Perhaps she would benefit from emergency surgery immediately, but they waited until morning and the patient died.

Individual Case Safety Report



10079170-01-00-02

546517

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

... History of insulin-dependent diabetes mellitus.
10. History of chronic kidney disease stage III.
11. Anxiety, depression disorder.

Individual Case Safety Report

10079170-01-00-03

Individual Case Safety Report

10170968-01-00-01

...ARY reporting of ...oduct problems and ...use errors

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See PRA statement on reverse

FDA USE ONLY
Triage unit sequence # 549795

Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	2 years old	☐ Female ☑ Male	23.3 lb or 10.6 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)
☐ Death: _____ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☑ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
04/11/2014	05/01/2014

5. Describe Event, Problem or Product Use Error

Patient underwent a fecal microbiota transplant (FMT) for a history of recurrent C. difficile on the morning of 4/4/2014. His CBC that afternoon showed a platelet count of 89,000. (b) (6) later (on (b) (6) he developed petechiae and was found to have a platelet count of 28,000. He required hospital admission for platelet transfusion.

CTU

MAY 13 2014

6. Relevant Tests/Laboratory Data, Including Dates

Platelet counts:
4/4/2014: 89,000
(b) (6) 28,000

CTU

MAY 13 2014

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

Inflammatory Bowel Disease
Recurrent C. difficile
(b) (6)

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Name: Stool from healthy donor used for FMT
Strength:
Manufacturer:

#2 Name
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 240 ml	once	via colonoscopy
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 4/4/2014
#2

4. Diagnosis or Reason for Use (Indication)
#1 Recurrent C. difficile
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Lay User/Patient
		☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date (mm/dd/yyyy)	7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Physician	☐ Manufacturer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☑		☐ User Facility ☐ Distributor/Importer

PLEASE TYPE OR USE BLACK INK

10455386-01-00-01

CBER

...UNTARY reporting of ...nts, product ...blems and ...oduct use errors

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See PRA statement on reverse.

Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence # 564281

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☐ Female ☑ Male	____ lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)
☐ Death: ____ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
07/31/2014	09/02/2014

5. Describe Event, Problem or Product Use Error

The patient is a 23 year old man with C-5 quadriplegia since a MVA in (b) (6) He had multiple recurrences of C. difficile since November 2013 after receiving an antibiotic for a UTI. He initially required hospitalization for the C. difficile infection. He was treated with several courses of vancomycin, including a vancomycin taper. Stool C. difficile PCR was positive on 5/5/14. Stool studies on 6/2/14 revealed no pathogens on culture, negative campylobacter antigen, negative Giardia antigen, Cryptosporidium EIA negative, C. difficile PCR positive.

6. Relevant Tests/Laboratory Data, Including Dates

Routine donor testing on 1/13/14, 2/25/14, 4/24/14 and 6/30/14 were all negative for stool O&P and Giardia (b) (4) Moreover, OpenBiome archives an aliquot of stool from every donation. The aliquot was pulled and stool O&P and Giardia (b) (4) were both negative on the stool sample that was used for this patient's transplant.

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

Past medical history positive for femoral DVT, osteomyelitis at donor iliac graft site, neurogenic bowel and bladder, and GERD.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Name: Human stool
Strength:
Manufacturer: OpenBiome

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 25 mL	once	nasogastric tube
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 6/26/14
#2

4. Diagnosis or Reason for Use (Indication)
#1 Recurrent C. difficile colitis
#2

6. Lot #	7. Expiration Date
#1 (b) (6)	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name: CTU
2b. Procode

3. Manufacturer Name, City and State
SEP 15 2014

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)
See p. 3

G. REPORTER (See confidentiality section on back)

(b) (6)

2014

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Physician	☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

B.5. Describe Event or Problem *(continued)*

He underwent fecal transplant on June 26, 2014 using donor stool from OpenBiome (donor (b) (6) specimen (b) (6) Despite the transplant he continued to have diarrhea. Subsequent testing on 7/31/14 revealed that his stool Giardia antigen was positive and stool C. difficile PCR was also positive. He was then treated with a course of metronidazole. Repeat testing on on 8/21/14 showed that the Giardia antigen was now negative, and C. difficile PCR was negative on 8/25/14. I spoke with the patient's mother this morning and she tells me that his diarrhea has resolved. This raises the question as to the source of the Giardia infection and whether the donor stool may have been the source. The patient has no recent travel history and has not drank water from any streams. Water is supplied to his home by a private company (they do not have city water and do not have a well). The patient's mother has discussed this with the local health department. With regards to the donor, screening has been performed every 2 months since January 2014 (see below) and all screening tests have been negative, including stool O&P exams and Giardia (b) (4)

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

Routine donor testing on 1/13/14, 2/25/14, 4/24/14 and 6/30/14 were all negative for stool O&P and Giardia (b) (4) Moreover, OpenBiome archives an aliquot of stool from every donation. The aliquot was pulled and stool O&P and Giardia (b) (4) were both negative on the stool sample that was used for this patient's transplant.

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

F. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (continued)*

baclofen, bisacodyl, dantrolene, docusate, famotidine, levalbuterol, loratadine, lorazepam, multivitamin, ondansetron, oxandrolone, oxycodone, promethazine, senna

Form Approved OMB No. 0910-0291, Expires 6/30/2015
see OMB statement on reverse.

10469117-01-00-01

r use by user-facilities, distributors and manufacturers ANDATORY reporting

Page 1 of 8

Mfr Report # (b) (6)

UF/Importer Report #

565038 FDA Use Only

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence

2. Age at Time of Event: 80 Years or Date of Birth:

3. Sex: ☑ Female ☐ Male

4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

☑ Death: (b) (6) (mm/dd/yyyy)
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 08/11/2014

4. Date of This Report (mm/dd/yyyy): 08/11/2014

5. Describe Event or Problem

80F with multiple major comorbidities (lymphoma, acute renal failure) and severe, complicated CDI (Horn Index 4). Pre-test probability of FMT success was low and non-response to FMT via GJ on background of no adverse events was reported.

Briefly, ongoing respiratory failure in rehabilitation facility (legoniella versus CHF) and transferred to hospital with diagnosis of pneumonia, in turn, treated with broad spectrum antibiotics. Diarrhea started after empiric antibiotics initiated in the rehabilitation facility. CDI positive and clinical picture of severe, complicated CDI including transient ileus but no toxic megacolon on CT. Patient treated with Vanco PO/PR, Flagyl and Fidaxomicin without benefit, and continued evidence of SIRS with pulmonary and GI sources implicated.

Continued on page 3

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

Patient had stool PCR positive for C. difficile on (b) (6) Patient had flexible sigmoidoscopy with pseudomembranous colitis on (b) (6)

CTU

SEP 22 2014

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

1. Lymphoma - chemotherapy 5 weeks prior including stress dose steroids
2. CHF - severity unknown
3. Recurrent pneumonias/respiratory failure with previous trach/PEG

Continued on page 3

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)

#1 OpenBiome 30mL Fecal Microbiota Preparation

#2

2. Dose, Frequency & Route Used

#1 30mL, Once, J-Tube

#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)

#1 08/08/2014

#2

4. Diagnosis for Use (Indication)

#1 Refract., svr complicate., CDI

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #

#(b) (6)

#2

7. Exp. Date

#1 02/07/2014

#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

Chemotherapy for lymphoma (5 weeks prior); Stress-dose glucocorticoids; Anti-C. difficile antibiotics including metronidazole, vancomycin, fidaxomycin; Levophed for blood pressure support

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

2b. Procode

3. Manufacturer Name, City and State

4. Model # | Lot # | 5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:

Catalog # | Expiration Date (mm/dd/yyyy)

Serial # | Unique Identifier (UDI) #

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

SEP 22 2014

10. Device Available for Evaluation? (Do not send to FDA) ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

(b) (6)

2. Health Professional? ☑ Yes ☐ No

3. Occupation: Physician

4. Initial Reporter Also Sent Report to FDA ☑ Yes ☐ No ☐ Unk.

10469117-01-00-02

Page 2 of 8

FDA USE ONLY

565038

1. Check One ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report ☐ Initial ☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*

Patient Code ____ - ____ - ____

Device Code ____ - ____ - ____

11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

12. Location Where Event Occurred ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

Name: OpenBiome

Address: (b) (4)

Email Address: safety@openbiome.org

2. Phone Number: 617-575-2201

3. Report Source *(Check all that apply)*

☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☑ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other: ____

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 09/04/2014

5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*

☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☐ Initial ☐ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)

9. Manufacturer Report Number

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction

2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation

3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use? ☐ Yes ☐ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*

Patient Code ____ - ____ - ____

Device Code ____ - ____ - ____

Method ____ - ____ - ____ - ____

Results ____ - ____ - ____ - ____

Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____

8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or **11.** ☐ Corrected Data

DSS

SEP 22 2014

5603038

FORM FDA 3500A (2/13) *(continued)*

Back to Item B.5 | Back to Item B.6 | Back to Item B.7 | Back to Item C.10 | Back to Item D.11

B.5. Describe Event or Problem *(continued)*

After informed consent by daughter (b) (6) FMP 30 via GJ after 4L PEG and pre-PPI with 8 hour d/c of anti-CDI therapy. No clinical response was noted and continued clinical decline. Two days post-FMT flexible sigmoidoscopy conducted to rule out ischemic and CMV colitis, and evidence of pseudo-membranes detected (note: no endoscopy conducted at time of diagnosis). Ongoing hypotension and clinical decline. Family requested withdrawal of active treatment with comfort care measures only, and patient expired. Cause of death believed to be multifactorial including respiratory failure and CDI. No objective adverse events from FMT were noted.

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)* *(continued)*

4. Recurrent CDI
- Approximately 6 episodes each following antibiotics most commonly for pneumonias
- Previous treatments include: Flagyl, Vanco and Vanco taper
- Vanco suppressive therapy initiated in rehab for unclear time period but negative CDI test and thus discontinued at some point prior to admission

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

DSS
SEP 22 2014

Other Remarks

Form Approved OMB No. 0910-0291, Expires: 6/30/2015
see OMB statement on reverse.

10469127-01-00-01

use by user-facilities,
istributors and manufacturers
NDATORY reporting

Mfr Report # (b) (6)

UF/Importer Report #

5605840 FDA Use Only

FORM FDA 3500A (2/13)

Page 1 of 25

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6) In confidence	or Date of Birth: (b) (6)	☐ Female ☑ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

☐ Death: ____ (mm/dd/yyyy)
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)
07/31/2014	09/19/2014

5. Describe Event or Problem

23M with C-5 paraplegia and recurrent CDI (modified Horn Index 3) and Giardia following FMT. Briefly, recurrent CDI non-responsive to standard therapy with positive CDI PCR on background of negative stool studies including Giardia antigen, Campylobacter antigen, Cryptosporidium EIA, culture. Underwent FMT via NG but continued to have diarrhea. Re-tested (Day 35 post-FMT) and positive for stool Giardia antigen and CDI PCR. Treated with course of metronidazole and repeat testing for both Giardia and CDI negative with subsequent clinical resolution.

CTU

SEP 22 2014

Continued on page 3

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

Regular donor testing on 01/13/2014, 02/25/2014, 04/24/2014, and 06/30/2014 were all negative for stool Ova/Parasite and Giardia (b) (4) The sample was collected on 04/15/2014, with negative screening results before and after collection.

In addition to this regular testing regimen, we save a frozen aliquot of every outgoing sample to allow retrospective investigations of potentially related

Continued on page 3

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

1. C-5 quadriplegia (MVA - (b) (6) complicated by neurogenic bladder and bowel treated with bisacodyl, senna, docusate at baseline
2. Femoral DVT
3. Osteomyelitis at donor iliac graft site
4. GERD
5. Recurrent CDI
- Multiple recurrences (>3), including 1 hospitalization, after antibiotics for UTI

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)

#1 OpenBiome 30mL Fecal Microbiota Preparation

#2

2. Dose, Frequency & Route Used	3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1 25mL, Once, NG Tube	#1 06/26/2014
#2	#2

4. Diagnosis for Use (Indication)	5. Event Abated After Use Stopped or Dose Reduced?
#1 Recurrent C. difficile colitis	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
(b) (6)	#1 12/10/2014	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

baclofen, bisacodyl, dantrolene, docusate, famotidine, levalbuterol, loratadine, larazepam, multivitamin, ondansetron, oxandrolone, oxycodone, promethazine, senna

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date (mm/dd/yyyy)	7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

(b) (6)

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Physician	☑ Yes ☐ No ☐ Unk.

10469127-01-00-02

FDA USE ONLY

5650470

1. Check One
☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report (mm/dd/yyyy)

9. Approximate Age of Device

10. Event Problem Codes (Refer to coding manual)
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ (mm/dd/yyyy)
☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home
☐ Nursing Home ☐ Ambulatory Surgical Facility
☐ Outpatient Treatment Facility
☐ Other: ____ (Specify)

13. Report Sent to Manufacturer?
☐ Yes ____ (mm/dd/yyyy)
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name
OpenBiome
Address
(b) (4)
Email Address
safety@openbiome.org

2. Phone Number
617-575-2201

3. Report Source (Check all that apply)
☐ Foreign
☐ Study
☐ Literature
☐ Consumer
☑ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer (mm/dd/yyyy)
09/04/2014

5.
(A)NDA # ____
IND # ____
BLA # ____
PMA/ 510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☐ Initial
☐ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)

9. Manufacturer Report Number

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No (Attach page to explain why not) or provide code:

4. Device Manufacture Date (mm/yyyy)

5. Labeled for Single Use?
☐ Yes ☐ No

6. Event Problem and Evaluation Codes (Refer to coding manual)
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/ Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
SEP 22 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995.
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

B.5. Describe Event or Problem *(continued)*

Successive donor testing has been pan-negative and safety aliquot used for patient's FMT negative for stool O&P and Giardia (b) (4) Patient had no recent travel/camping history or ingestion of any water from streams. Unclear if any rehabilitation pool exposures. Patient does have wells but water supplied by private company and local public health department inquiring.

Given safety sample used in actual FMT was negative for O&P and Giardia (b) (4) it seems unlikely the source of the event. The possibility of a false positive Giardia test (with ongoing CDI) or an environmental source exposure is possible given the clinical context.

Back to Item B.5

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

adverse events. Upon learning of the possible AE from (b) (6) , OpenBiome pulled the safety aliquot and sent it to a CLIA-certified laboratory for stool O&P and Giardia (b) (4) both of which were negative.

(b) (4) tests for Giardia, (b) (4) and Ova/Parasite were performed on safety aliquot of stool for Donor (b) (6) Specimen (b) (6) Tests were performed on 08/30/2014. Results were as follows:
(1) Ova + Parasite Exam: "No ova, cysts, or parasites seen."
(2) Giardia lamblia (b) (4) "Negative"
Please see attached test results for supporting documentation.

Back to Item B.6

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)* *(continued)*

Back to Item B.7

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)* *(For continuation of C.10 and/or D.11; please distinguish)*

Back to Item C.10

Back to Item D.11

Other Remarks

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SEP 22 2014

Individual Case Safety Report

10785361-01-00-01

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Form Approved: OMB No. 0910-0291, Expires: 6/30/2016
See PRA statement on reverse.

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

...ARY reporting of adverse events, product problems and product use errors

Page 1 of 2

FDA USE ONLY
Triage unit sequence #: 582796

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) years old	☑ Female ☐ Male	97 lb or 44.4 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defective/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)
☑ Death: (b) (6) (mm/dd/yyyy)
☐ Life-threatening
☐ Hospitalization - Initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
02/06/2015	02/09/2015

5. Describe Event, Problem or Product Use Error

Patient was deemed eligible for FMT study based on prior hospitalization and prior antibiotic failure. At appointment, patient's overall well-being was reported as "fair." Patient completed FMT procedure on 23-Jul-2014 with a non-related donor. Patient completed 24-hour follow-up phone call on 24-Jul-2014. Patient was experiencing slight fatigue and answered negatively for fever, abdominal pain, nausea, vomiting, diarrhea, and loss of appetite. On 31-Jul-2014, patient's daughter completed 1-week follow-up phone call and answered negatively on patient's behalf for abdominal pain, hospitalization, fevers, chills, fatigue, loss of appetite, and diarrhea...

6. Relevant Tests/Laboratory Data, Including Dates

N/A

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

Congestive Heart Failure
Atrial Fibrillation
Pacemaker
Hypertension
Seizure
Altered mental status

PLEASE TYPE OR USE BLACK INK

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)

☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Name:
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 300 mL	Once	Colonoscopy
#2		

3. Dates of Use (if unknown, give duration) from/to (or best estimate)	9. Event Abated After Use Stopped or Dose Reduced?	10. Event Reappeared After Reintroduction?
#1 07/23/2014	#1 ☐ Yes ☐ No ☑ Doesn't Apply	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☑ Doesn't Apply	#2 ☐ Yes ☐ No ☑ Doesn't Apply

4. Diagnosis or Reason for Use (Indication)
#1 Recurrent C. Difficile Infection
#2

6. Lot #	7. Expiration Date	8. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Fecal Microbiota Transplant

2. Common Device Name	2a. Procode
Stool Transplant	~~CHU~~ FEB 10 2015

3. (b) (6), (b) (4)

4. Model #	Lot #	5. Operator of Device
N/A	N/A	☑ Health Professional
Catalog # N/A	Expiration Date (mm/dd/yyyy) N/A	☐ Lay User/Patient
Serial # N/A	Unique Identifier (UDI) # N/A	☐ Other:

6. If Implanted, Give Date (mm/dd/yyyy)	7. If Explanted, Give Date (mm/dd/yyyy)
07/23/2014	

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☑ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER CONCOMITANT MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)
Vitamin B12 (3/10/2012 - (b) (6)
Furosemide (11/25/2014 -

G. REPORTER (see confidentiality section on page 2)

1. Name and Address

(b) (6), (b) (4) 015

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Physician	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

 Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

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MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

FOR VOLUNTARY reporting of adverse events and product problems

B.5. Describe Event or Problem *(continued)*

Patient had experienced formed bowel movements. On 9/15/2014, patient completed a follow-up appointment and noted occasional increased gas. Patient's well-being was reported as "good." Vitals signs were BP (123/64) and pulse (60). Patient was advised to try simethicone (Gas X) for gas/bloating. Between (b) (6) patient was hospitalized for congestion and evaluation of altered mental status. Patient was having dinner and appeared to be 'glazy eyed', therefore, patient was transported to ER department. Neurology was consulted and symptoms were thought to be secondary to complex partial seizures. A CT scan was obtained and patient was started on IV antibiotics and admitted to medicine floor for further evaluation. CT scan did not have any clinically significant changes. Patient was started on Depakote to help with neurological symptoms and discharged. On (b) (6) Infectious Disease was contacted because patient developed a temperature (99.6oF) with lethargy and dehydration. Patient was started on IV fluids and instructed to start vancomycin and ceftazidime. Patient continued to develop more congestion and began developing trouble swallowing thin and thick liquids. Patient was hospitalized (b) (6) and discharged on (b) (6) Patient passed away on (b) (6) Upon calling to complete 6-month phone call on 20-Jan-2015, research staff was informed that patient had passed away. Based on patient's previous medical history and lack of abdominal/bowel symptoms during post-FMT hospitalizations, it is unlikely that the adverse event is related to study procedure or FMT.

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)* *(continued)*

F. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)* *(continued)*

Depakote (10/14/2014 -
Torsemide (11/21/2013 - (b) (6)

DSS
FEB 10 2015

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Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See PRA statement on reverse.

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

FDA USE ONLY
Triage unit sequence #: 582797

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) years old	☑ Female ☐ Male	130 lb or 59.1 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defect/malfunction)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)
☑ Death: (b) (6) (mm/dd/yyyy)
☐ Life-threatening
☐ Hospitalization - Initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
02/06/2015	02/09/2015

5. Describe Event, Problem or Product Use Error

Patient was screened for FMT study 25-Nov-2013, and completed the FMT procedure on 11-Dec-2013 using a non-related donor. At 24-hour follow-up phone call, patient was experiencing mild fatigue. Daughter answered negatively on patient's behalf for hospitalization, abdominal pain, loss of appetite, constipation, diarrhea, fevers, chills, or nausea. At 1-week follow-up phone call, patient was experiencing mild bloating/gas/abdominal discomfort. On 28-Jan-2014, patient completed 4-week follow-up visit, and caregiver reported that patient's stools were formed, appetite was excellent, and there were no recent hospitalizations...

6. Relevant Tests/Laboratory Data, Including Dates

Fecal Lactoferrin (04/26/2014) - positive
C. Difficile Detection PCR (04/26/2014) - negative

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

Left leg ulcer
Urinary tract infections
C. Difficile
Hypertension
Atrial fibrillation

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Name:
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 200 mL	Once	Upper Endoscopy
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1 11-DEC-2013	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☑ Doesn't Apply

4. Diagnosis or Reason for Use (Indication)	8. Event Reappeared After Reintroduction?
#1 Recurrent C. Difficile Infection	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☑ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Fecal Microbiota Transplant

2. Common Device Name: Stool Transplant

2a. Procode: CTU

(b) (6), (b) (4)

FEB 10 2015

4. Model #	Lot #	5. Operator of Device
N/A	N/A	☑ Health Professional
Catalog # N/A	Expiration Date (mm/dd/yyyy) N/A	☐ Lay User/Patient ☐ Other:
Serial # N/A	Unique Identifier (UDI) # N/A	

6. If Implanted, Give Date (mm/dd/yyyy)	7. If Explanted, Give Date (mm/dd/yyyy)
12/11/2013	

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☑ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER CONCOMITANT MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)
Levothyroxine (12/23/2013 - (b) (6)
Warfarin (1/7/2014 (b) (6)

G. REPORTER

(b) (6), (b) (4)

015

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Physician	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

 Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

582797

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The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events and product problems

B.5. Describe Event or Problem *(continued)*

Patient completed a second follow-up appointment on 25-Mar-2014 due to complaints of weakness. Bowel movements were now semi solid and more frequent. Patient developed an infection of the right calf and was placed on topical antibiotics. In addition, caregiver noted that patient had an increased pulse rate and that patient was now in hospice. Patient was noted has having tachycardia and it was recommended that patient was taken to ER; however, daughter declined since patient had hospice status. Patient's daughter was asked to follow-up with PCP for rapid heart rate. Vital signs were BP (123/97) and pulse (157). On (b) (6) patient presented to clinic for wound assessment. Upon arrival to office, patient was not responsive. Patient was evaluated (no pulse was found) and patient was pronounced deceased upon arrival. Sub-investigator began calling subject for 6-month follow-up in June 2014, however, patient's family was unresponsive to research staff calls. Patient was marked as lost to follow-up until January 2015 when research staff checked patient's EMR and noted that patient was deceased.

Based on patient's medical history and concomitant illnesses (right leg infection, left leg ulcer, urinary infections), it is unlikely that the adverse event is related to study procedure or intervention (FMT).

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)* *(continued)*

F. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)* *(continued)*

Metroprolol (12/30/2013 - (b) (6)
Risperidone (1/7/2014 -
Tramadol (12/9/2013 - (b) (6)
Cholecalciferol/Vitamin D3 (11/2/2013 - (b) (6)
Ascorbic Acid (10/3/2013 - (b) (6)
Mirtazapine (9/25/2013 -
Omeprazole (9/4/2013 - (b) (6)
Collagenase (12/26/201:

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Individual Case Safety Report

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Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

1/4

FDA USE ONLY
Triage unit sequence # 582873

Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	71 Years (b) (6)	☑ Female ☐ Male	119 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
02/02/2015	02/10/2015

5. Describe Event, Problem or Product Use Error
See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
See page 4/3 for complete text.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Fecal Transplant
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1
#2

4. Diagnosis or Reason for Use *(Indication)*
#1
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU

3. Manufacturer Name, City and State

FEB 11 2015

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
		☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)
See page 5/4 for complete text

G. REPORTER *(See confidentiality section on back)*

1. Name and Address

(b) (6), (b) (4)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Medical Doctor (Physician)	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

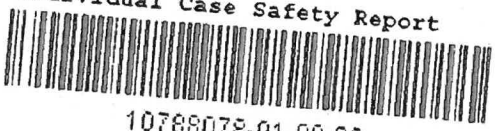
PLEASE TYPE OR USE BLACK INK

B.5. Describe Event or Problem *(continued)*

582873

The patient has a history of severe pouchitis characterized by abdominal cramping, diarrhea and dehydration. Her longest remission has been 3 weeks. She has recurrent bouts of pouchitis which she ends up in the Emergency Department for hydration and antibiotics. I received information on January 19, 2015 from her physician that she began having a flair and would go on vancomycin. After a few days she felt better, but she usually relapses at 5 days. She went off her antibiotics on January 24. She had a fecal transplant on (b) (6), (b) (4) on January 27, 2015. She noted having continued cramping and diarrhea as before, but the cramps were more intense. A few days later she went to Emergency Department and she was admitted for antibiotics and IV fluids. She was in the hospital 36 hours and is doing better now.

Individual Case Safety Report



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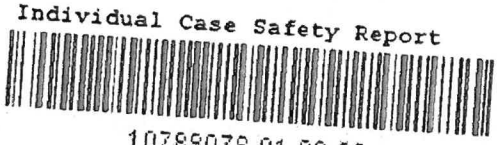
B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

ulcerative colitis
total proctocolectomy with J pouch ileoanal anastomosis

582873

Individual Case Safety Report



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F. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (continued)*

One fecal transplant on January 27, 2015

582873

Individual Case Safety Report

10788078-01-00-04

Individual Case Safety Report 44 AM PAGE 2/003 Fax Server

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CBER

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

Page 1 of 2

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See PRA statement on reverse.

FDA USE ONLY
Triage unit sequence #: 586101

A. PATIENT INFORMATION

1. Patient Identifier | 2. Age at Time of Event or | 3. Sex | 4. Weight
(b) (6) | | ☐ Female ☒ Male | 166 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:
1. ☒ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)
☒ Death: (b) (6) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 03/01/2015
4. Date of this Report (mm/dd/yyyy): 03/03/2015

5. Describe Event, Problem or Product Use Error

Acute, severe C. diff infection in an immuno-compromised patient who did not respond to conventional Rx, received FMT, and died (b) (6) later.

6. Relevant Tests/Laboratory Data, Including Dates

C diff ☒ 2/15/2015 (pre-)
C diff ☒ 3/1/2015 (post-)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

Vasculitis, therapy w/ infliximab + prednisone, renal (urethra on dialysis, age 81

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
☐ Yes ☒ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Name: Stool
Strength:
Manufacturer: OPEN BIOME
#2 Name:
Strength:
Manufacturer:

2. Dose or Amount | Frequency | Route
#1: 250 ml | x1 | 2/27/2015 colonoscopy
#2:

3. Dates of Use (if unknown, give duration) from/to (or best estimate)
#1: 2/27/2015
#2:

4. Diagnosis or Reason for Use (Indication)
#1: Severe C. diff
#2:

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #: #1: #2:
7. Expiration Date: #1: #2:
8. NDC # or Unique ID:

E. SUSPECT MEDICAL DEVICE

1. Brand Name: N/A
2. Common Device Name:
2b. Procode: CTU
3. Manufacturer Name, City and State:

MAR - 9 2015

4. Model #:
Lot #:
5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:
Catalog #:
Expiration Date (mm/dd/yyyy):
Serial #:
Unique Identifier (UDI) #:
6. If Implanted, Give Date (mm/dd/yyyy):
7. If Explanted, Give Date (mm/dd/yyyy):
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor:

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

N/A

G. REPORTER (See confidentiality section on back)

(b) (6)

2. Health Professional? ☒ Yes ☐ No
3. Occupation: MD
4. Also Reported to: ☒ Manufacturer ☐ User Facility ☐ Distributor/Importer
6. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

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FORM FDA 3500 (2/13) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

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586101

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

(CONTINUATION PAGE)

For VOLUNTARY reporting of adverse events and product problems

B.5. Describe Event or Problem *(continued)*

81 yo man w/ acute diarrhea in the setting of vasculitis treated w/ rituximab/prednisone, C. diff ⊕, who did not respond to vancomycin po & by enema & IV metronidazole & received FMT by colonoscopy (which showed severe pseudo-membranous colitis), improved quickly, with ⊖ stool C.diff, then became abruptly, severely ill, with hypoxia & acidosis, & died.

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

2/15/2015 stool C. diff ⊕ C diff strain: 027/NAP1/B1

3/1/2015 " " ⊖

Day of death glucose 33, lactate 3.6, abd x-ray neg for perforation

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Renal failure

Immunosuppression

DM2

Advanced age

F. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (continued)*

None

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Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See PRA statement on reverse.

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product use errors

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Adverse Event Reporting Program

Page 1 of 2

FDA USE ONLY
Triage unit sequence #: 605552

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) — In confidence
2. Age at Time of Event or Date of Birth: (b) (6)
3. Sex: ☐ Female ☑ Male
4. Weight: 162.8 lb or 74 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:
1. ☑ Adverse Event ☐ Product Problem (e.g., defective/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)
☐ Death: _____ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 04/13/2015
4. Date of this Report (mm/dd/yyyy): 06/30/2015

5. Describe Event, Problem or Product Use Error
86 y/o man with PMHx of Klebsiella pneumonia urinary tract infection (10/2014), ESRD on HD (since 8/2014), DM, CAD s/p CABG, CHF (EF 45%), HTN with recurrent, severe, refractory C. difficile infection following antibiotic treatment for otitis media (9/2014, 10/2014, 1/2015) who had a fecal Microbiota Transplant perfor... 3/30/15 with donor stool from Open Biome (Item (b) (6) Unit ID (b) (6) exp 9/24/15). Patient was doing well initially after transplant with daily formed bowel movement, which was documented on a phone note on 4/2/15. Approximately 1 week after FMT, patient developed hematuria and was referred to the Emergency Room.

6. Relevant Tests/Laboratory Data, Including Dates
Stool Culture 4/13/15: Salmonella Group C1
Blood Culture 4/13/14: No growth after 5 days
C. difficile 4/13/15, 1/9/15, 10/14/14, 9/12/14: Detected by PCR for Toxin B Gene or EIA for C. difficile toxin A/B
Stool Culture 1/9/15 and 1/15/15: No Salmonella, Shigella, Campylobacter or Yersinia Isolated

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
1. Severe, recurrent CDI following antibiotic treatment for otitis media (9/2014, 10/2014, 1/2015).
2. End-Stage Renal Disease on hemodialysis (since 8/2014)
3. Type 2 DM
4. Coronary heart disease (previous CABG)
5. Congestive heart failure (EF 45%)
6. Hypertension

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Name: Donor Stool (Item #: (b) (6) Unit ID: (b) (6)
Strength: 250mL
Manufacturer: Open Biome

#2 Name:
Strength:
Manufacturer:

	2. Dose or Amount	Frequency	Route
#1	250mL stool	Once	Colonoscopy
#2			

3. Dates of Use (if unknown, give duration) from/to (or best estimate)
#1 03/30/2015
#2

4. Diagnosis or Reason for Use (Indication)
#1 Severe recurrent C. difficile infection
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

	6. Lot #	7. Expiration Date
#1	(b) (6)	09/24/2015
#2		

(b) (6) Use ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: N/A
2. Common Device Name
2b. Procode
3. Manufacturer Name, City and State
4. Model #
Lot #
5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:
Catalog #
Expiration Date (mm/dd/yyyy)
Serial #
Unique Identifier (UDI) #
8. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
9. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 9, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

2. Health Professional? ☑ Yes ☐ No
3. Occupation: Physician
4. Also Reported to: ☑ Manufacturer ☐ User Facility ☐ Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

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FORM FDA 3500 (2/13) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B.5. Describe Event or Problem *(continued)*

He was admitted to (b) (6) on (b) (6) days s/p FMT) with sepsis from emphysematous cystitis (urine culture: Klebsiella pneumoniae ssp pneumoniae. Patient was initially treated with ceftriaxone 1g IV daily and had persistently formed bowel movements until treatment with antibiotics. He then developed loose stools secondary to recurrent C. difficile and Salmonella Group C1 without bacteremia. He was treated with a prolonged course of trimethoprim-methoxazole and cephalexin as well as vancomycin 500mg PO q6.

Two months after hospitalization, the patient was evaluated in GI clinic. He completed his antibiotics including vancomycin without any clinical signs of infection. He has formed daily bowel movements without abdominal pain. He had no identifiable risk factors for salmonella infection.

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

Urine Culture 4/9/15: >100,000 CFU/mL Klebsiella pneumoniae ssp pneumoniae
Urine Culture 10/24/14: >100,000 CFU/mL Klebsiella pneumoniae ssp pneumoniae

CT A/P (b) (6) IMPRESSION: 1. Thickwalled urinary bladder with surrounding inflammatory change. Foci of gas are present within the bladder lumen, and along the bladder wall. While some of the mural foci may be within diverticula, others appear to be intramural. Additionally, two small foci of gas are noted adjacent to the bladder, but completely external to it. At least one of these foci appears to be venous (image 46 of the coronal series), and the other likely also is as well (image 78 series 3). No free fluid around the bladder to suggest frank bladder perforation. Overall findings are consistent with emphysematous cystitis. This was reported to (b) (6) at 7:34 a.m. on (b) (6) 2. Adjacent sigmoid colon is unremarkable, without evidence of inflammation. 3. Bilateral pleural effusions. 4. Nodular liver contour suggestive of parenchymal disease. 5. Abnormal lymph node anterior to the right hip, just lateral to the sartorius muscle, measuring 17 mm, nonspecific. This may be reactive, a metastatic node cannot be excluded.

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

7. Klebsiella pneumoniae urinary tract infection

F. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (continued)*

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(b) (6) P 2/3

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See PRA statement on reverse.

The FDA Safety Information and Adverse Event Reporting Program

VOLUNTARY reporting of adverse events, product problems and product use errors

Page 1 of 3

FDA USE ONLY

Triage unit sequence # 608168

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In confidence
2. Age at Time of Event or Date of Birth: (b) (6)
3. Sex: ☐ Female ☑ Male
4. Weight: ____ lb or 152.5 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions) ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)
   - ☐ Death: ____ (mm/dd/yyyy)
   - ☑ Life-threatening
   - ☑ Hospitalization - initial or prolonged
   - ☑ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☑ Other Serious (Important Medical Events)
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 6/30/2015
4. Date of this Report (mm/dd/yyyy): 7/30/2015

5. Describe Event, Problem or Product Use Error

Pt with h/o recurrent c.diff presented to ER with 5 day h/o diarrhea/blood in stool. Received Openbiome Stool Transplant 6/25/15. Had colonoscopy (b) (6) showed moderate internal hemorrhoids and mid/proximal descending colon area of deep ulceration.

6. Relevant Tests/Laboratory Data, Including Dates

CT abd (b) (6) → inflammation in the ascending of the sigmoid colon. Edema of inflammation of colitis

Biopsy immuno histochemistry for CMV shows a few positive cells

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

Cdiff 6/9/15 + PCR 7/1/15 negative

6/30 WBC 8.4 K
INR 1.3
Cr 2.24 (baseline)
7/2 CRP 151.5

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Name: (b) (6) unit ID (b) (6)
Strength:
Manufacturer: Openbiome (OAS: Fecal Microbiota)

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount / Frequency / Route

	Dose or Amount	Frequency	Route
#1	250 ml	once	Feeding Tube
#2			

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 6/25/2015
#2

4. Diagnosis or Reason for Use (Indication)
#1 Recurrent C diff.
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1 (b) (6)
#2

7. Expiration Date
#1 8-4-2015
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

CTU

2. Common Device Name

2b. Procode

JUL 31 2015

3. Manufacturer Name, City and State

4. Model #
Lot #
Catalog #
Expiration Date (mm/dd/yyyy)
Serial #
Unique Identifier (UDI) #

5. Operator of Device
☐ Health Professional
☐ Lay User/Patient
☐ Other:

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address
Name:
Address:

DSS

JUL 31 2015

City: State: ZIP:
Phone # E-mail

2. Health Professional? ☐ Yes ☐ No
3. Occupation
4. Also Reported to:
☐ Manufacturer
☐ User Facility
☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

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608168

11330369-01-00-02

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...ARY reporting of
adverse events and product problems:

MEDWATCH
The FDA Safety Information and
Adverse Event Reporting Program

B.5. Descriptive Event or Problem (continued)

Readmitted (b) (6) with recurrent bloody diarrhea and anemia. (b) (6) ganciclovir treatment in addition to receiving PRBC transfusion (3 units). Was discharged after 1 week ganciclovir with oral valganciclovir for the... On (b) (6), he was readmitted with sepsis like syndrome. Blood cultures were positive for E. coli. CT of abdomen at radiology impressive. Ultrasound of gallbladder (b) (6) with moderate distention 3 stones, wall thickening or pericholecystic fluid collection. Ultimately taken to OR for laparotomy and probable colectomy. Postop dx: fulminant colitis, descending colon perforation and intra-abdominal sepsis. Path was suggests: "late sequela of the underlying disease process. No specific features are identified to suggest a cause for the ulcerations."

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

STOOL negative for campylobacter, c diff toxin A/B, Plesiomonas shigelloides, salmonella spp, vibrio sp, vibrio cholerae, yersinia enterolitica, enteroaggregative E. coli, enteropathogenic E. coli, enterotoxigenic E coli, shiga-like toxin producing E. coli, Shigella/Enteroinvasive E. coli, cryptosporidium, cyclospora cayetanensis, Entamoeba histolytica, giardia lamblia, adenovirus F 40/41, adenovirus, norovirus GI/GII, rotavirus & sapovirus.

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

Individual Case Safety Report

11492273-01-00-01

OCET

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See PRA statement on reverse.

...RY reporting of duct problems and ...se errors

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence #
1614108

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	87	☑ Female ☐ Male	____ lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)
☑ Death: (b) (6) (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
08/01/2015	08/24/2015

5. Describe Event, Problem or Product Use Error

87 y/o F admitted with severe, complicated C difficile infection (CDI) which did not respond to 2 weeks of standard medical therapy (IV metronidazole/PO vanco. This was her 3rd C diff episode. She underwent FMT on 07/02/2015 with some improvement, but needed to resume vanco again afterwards for rising leukocytosis and diarrhea. She was discharged to a rehab facility for ongoing issues of weakness, debilitation, mental status decline. FMT repeated as outpatient by sigmoidoscopy on 07/23/15 (Openbiome (b) (6) ; procedure uncomplicated. Vanco was held. She declined afterward with confusion, pain (unclear where as not lucid enough to indicate), continued diarrhea and

6. Relevant Tests/Laboratory Data, Including Dates

none

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

diabetes, congestive heart failure (diastolic disfunction), delerium, anxiety, pleural effusion, hyperlipidemia, h/o breast cancer

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Name: Donor Stool (Openbiome (b) (6) -used 7/23/15
Strength:
Manufacturer: Openbiome

#2 Name: Donor stool (Openbiome (b) (6) -used 7/2/15
Strength:
Manufacturer: Openbiome

2. Dose or Amount	Frequency	Route
#1 250 cc		sigmoidoscopy
#2 250 cc		sigmoidoscopy

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 07/02/2015
#2 07/23/2015

4. Diagnosis or Reason for Use (Indication)
#1 severe, recurrent & refractory C difficile infection
#2 recurrent C difficile infection

6. Lot #	7. Expiration Date
#1 (b) (6)	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☑ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☑ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name | 2b. Procode: CTU

3. Manufacturer Name, City and State

SEP 10 2015

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date (mm/dd/yyyy) | 7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

metformin, lisinopril, clonazepam, furosimide, gabapentin, insulin, mirtazepine, S. boulardii,ibuprofen

G. REPORTER (See confidentiality section on back)

(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Physician	☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

(b) (6)

B.5. Describe Event or Problem *(continued)*

abdominal distension. She did not undergo any diagnostic evaluation for this decline. The family decided to pursue hospice, where she died or (b) (6) days post second FMT).

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)* *(continued)*

F. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)* *(continued)*